1/16/07

New York State Department of Health Comments on the Final Draft Report of the Interstate Workgroup on Evaluating Atlantic Coastal Advisories for Striped Bass and Bluefish Based on PCBs (12/15/2006)

Several different types of information need to be considered when developing a fish consumption advisory. Information on contaminant levels in fish, by geographic area and by size and species, needs to be displayed. The health risks associated with eating fish need to be considered for both the general population and for segments of the population that might be at higher risks. In addition, the health benefits need to be evaluated so that the health risks and benefits can be compared. The present version of the document does not discuss these issues in sufficient detail for a risk manager to make an informed decision.

General Comments

1. We agree with the objective to evaluate the feasibility of a common fish consumption advisory for striped bass and bluefish in the Atlantic coastal states. However, this report does not adequately evaluate the available data for PCB levels in striped bass and the importance of fish size and geographical locations to permit an advisory that will help anglers derive the benefits of fish consumption while minimizing the risks from PCB contamination. For example, the PCB levels in striped bass caught in coastal areas somewhat off-shore and along the ocean shoreline appear to be less contaminated than fish caught in and near many estuaries and bays, yet the data have not been presented to clearly address this pattern. Smaller fish generally have lower PCB levels than larger fish, and the effect of size on PCB levels needs to be evaluated. And most importantly, data from recent years (since 2002) show that PCB levels have declined over the past 10 years. Data are just now coming in for striped bass collected by CT and NY in Long Island Sound during the summer of 2006 that support this observation. The report does not recognize and describe these patterns; thus, the recommended advisories do not distinguish fish which should have less restrictive advisories (lower PCB levels) from fish that should have more restrictive advisories (due to higher PCB levels).

Unfortunately, the primary conclusion of the Data Subworkgroup as written suggests that the data are not adequate for describing regional patterns of contamination. If that is the case, how can the states agree on a common advisory?

2. The report does not adequately characterize the health benefits and risks from consuming striped bass and bluefish. The Uncertainties and Research Recommendations section in the Conclusions and Recommendations chapter does not even acknowledge that health effects include benefits as well as risks. The recent National Academy of Science report ("Seafood Choices: Balancing Benefits and Risks) and the JAMA article and Patient Page on the risks and benefits of consuming fish have been ignored by this report. The report should explicitly address this issue for coastal bluefish and striped bass. On 1/9/07 Eric Frohmberg sent workgroup members a note on this topic. In our view, the note and attachment are not sufficient to address this issue.

3. The many different analytical methods that states are using to measure PCBs in fish are briefly described, but no discussion explains whether the different analytical methods are effectively comparable to one another. Several states have split fish samples and analyzed them by a couple of different methods, but whether the results differ or not should has not been discussed in the report.

4. The chapter on the biology of striped bass and bluefish is interesting, but the relevance of much of the information to establishing consumption advisories is not clear. For example, how should advisories be affected by the dietary habits of either species? A further complication in this chapter is the discussion of regulations and size limits that are in inches while all the contaminant data are presented in metric values. The recommendations about the need for sampling programs in each state to adequately represent the recreational catch and possible subpopulations of fish that may be more or less contaminated than others is important. However, the data for striped bass and bluefish presented in the document have not been clearly assessed and described to know whether this is true or not.

5. We have two major concerns with the health effects section. The first is that the document departs from a standard risk-based approach without considering it in detail. Risk-based approaches are being used by EPA, the Great Lakes states, FDA and other states in developing fish consumption advisories. Furthermore, guidance for potential exposures to chemicals in other media (air, water, soil, other foods, etc.) is usually derived using risk assessment. The traditional use of risk assessment needs to be included as an option that is fully explored, especially since health benefits should be examined in light of health risks. The second major concern is the use of the Oswego study as the basis for an advisory for sensitive populations. Given the importance of the Oswego study in this report, its limitations should be fully discussed and other relevant data considered before it (either alone or in combination with other data) is used as a basis for developing advisories..

6. In general, the document should contain a discussion of the uncertainties associated with the conclusion that correlations between the degree of neurological effects in children and prenatal exposure as determined by PCB cord serum levels represent cause and effect. This is a controversial conclusion (see “Psychology in the Schools”, Volume 41 , Issue 6, 2004- Special Issue: PCBs and Developmental Outcomes: A Critical Debate). Information on the strengths/limitations of the various relevant studies would be a valuable resource to risk managers in their analysis of the health risks and benefits of fish consumption

For example and in particular, the results of the neurobehavioral tests on the Oswego cohort show that dose-response data do not consistently indicate effects at all measured PCB cord serum levels. The data suggest that neurological effects appear more consistently in the children at the highest tertile of PCB cord blood than in children at the mid-tertile group. Some effects appear absent (or undetected) in the lowest tertile group. Thus, the subworkgroup’s conclusion that effects are occurring “at body burdens typical of women in the general population” is too broad, and inconsistent with some of the data. Some effects may be present, but only among the study children with the highest PCB cord serum levels. For other effects, the dose-response appears linear across all tertiles, which could suggest effects at all measured PCB cord serum levels. However, there is less confidence in the conclusion of a cause-and-effect

relationship at these lower levels given uncertainties in the shape of the dose-response curve at low cord serum levels, particularly in the absence of statistical support (i.e., p-values < 0.05) or other evidence. Thus, the subworkgroup's conclusion that neurological effects are occurring "at body burdens typical of women in the general population" should be more carefully worded, and should include a definition of body burden.

Another area where additional discussion would be helpful to risk managers is the weight-of-evidence in support of the subworkgroup's conclusion that the Oswego cohort has PCB body burdens similar to those of the general US population. Although Longnecker et al. (2003) estimated the serum levels of PCB 153 in the Oswego Cohort using the breastmilk data and the resultant distribution data are similar to the distribution of PCB 153 in the general US population (i.e., the NHANES sample), this is but one congener and whether distributions of other congeners in the two populations are also similar is unknown. Moreover, there remains some uncertainty in the estimation of serum levels of PCB 153 from breastmilk levels of PCB 153. In addition, the importance of PCB 153 or any other congener in causing neurological effects observed in the Oswego cohort is unknown, which further weakens confidence in the conclusion that effects are occurring "at body burdens typical of women in the general population."

In summary, additional scientific and technical support for the decision to depart from a risk-based approach needs to be presented before a decision can be made as to whether such an approach is advisable and scientifically defensible.

7. The Health Effects Subworkgroup also recommended the future use of the Oswego (or other epidemiological) studies in the derivation of a reference dose for PCBs based on benchmark dose (BMD) analyses of the relationships between body burden (maternal and/or cord blood) and various neurological effects. We support such an effort as part of the re-examination of the present RfD and echo the workgroups concern that several problems may be difficult to solve. For example, human studies based on biomonitoring data do not provide good estimates of daily intake, which is the dose metric that must be used in fish advisories. The critical problem is how do we confidently and accurately estimate daily intake from biomonitoring data (e.g., serum levels), and what PCB dose metric do we use (e.g., Aroclors, specific congener or groups of congeners, or higher chlorinated congeners)? In particular, the Oswego Cohort poses special problems since the primary PCB dose metric used in the study was cord serum levels of the most persistent and highly chlorinated PCB congeners. There are also problems with the identification of a point-of-departure as the starting point for a RfD derivation. These would include, but are not limited to, what to use as the critical effect and the PCB dose metric, what type of point-of-departure to use (NOEL or benchmark dose), and, if using a benchmark dose, what percentage change should be considered adverse. Given the national scope of PCB contamination and the complexity of assessing their risk, we support urging the US EPA to accelerate its reexamination of the current reference dose for PCBs.

8. We disagree with the Health Effects subworkgroup's conclusion that "The more recent data from several epidemiological studies would provide a more appropriate basis of a noncancer RfD for PCBs than would the animal studies currently used (page 90)." The subworkgroup does not adequately discuss its reasons for dismissing the animal studies (i.e., rhesus monkey studies) in

the derivation of a RfD (reference dose) for PCBs. Just because the studies used animals and were conducted years ago does not disqualify them for use alone or in conjunction with more recent human studies as the basis for a RfD. Epidemiological studies have inherent weaknesses (e.g. estimating actual exposure or dose) when used in quantitative risk assessment

9. The advisory recommendation for high risk groups to EAT NO coastal striped bass or bluefish is based on the assumption that striped bass and bluefish have far higher PCB levels than other foods and thus implies that any consumption of these fish would result in uniquely elevated increases in PCB exposures. There are two problems with this assumption:

- PCB levels in coastal striped bass and bluefish are not properly characterized (see Comment 1). Based on some of the states' more recent data and data that are now coming in from 2006 Long Island Sound collections, PCB levels in bluefish (particularly smaller ones) and striped bass appear to be lower than they are characterized in this report.
- The table listing PCB levels in other foods is far from comprehensive (the report concedes that more data are needed.) Moreover, based on the limited data provided and the relatively high consumption rates of some foods (e.g., roasted chicken breast), many foods may make substantial contributions to PCB exposure. For example, Table 6-1 on page 146 indicates that a sample of roasted chicken breast contained 0.032 ppm PCBs. If a person ate 8 ounces of a food containing that PCB concentration twice per week, their average daily PCB intake would be 1.5 mg. A person eating 8 ounces per month of a food containing 0.2 to 0.5 ppm PCBs (approximate range of concentrations in more recent collections of coastal bluefish and striped bass) would have average daily PCB intakes of 1.5 and 3.7 mg, respectively.

10. Please replace the text in the box on page 127 (re: NYSDOH fish advisories) with the following: "When reviewing fish PCB data, the New York State Department of Health considers the following:

- fish contaminant levels, including fish sampling characteristics (e.g., number and type of samples, species, age, length, percent lipid, sample location, etc.);
- health risks;
- populations at greater potential risk;
- the FDA marketplace standard;
- health benefits; and
- risk communication issues.

Minor Comments

1. The following statements appear in the executive summary:

- "The objective of the Subworkgroup was to analyze the feasibility of a consistent advisory based on PCB contaminants for all of the Atlantic coastal states;"
- "Hence the workgroup proposes the following advice as a consideration as a starting point of further discussion."

This report goes much further than these passages would indicate because it develops and advocates a single set of advisories based on a novel approach that departs from traditional risk assessment and does not consider the benefits of fish consumption.

2. Moreover, the executive summary also states: “The states involved in drafting this report will strive for a consensus about how to implement the recommendations in this report.” This statement implies an acceptance of the proposed advisory approach before state agency approval of that process has occurred.

3. We agree with the report's suggestion that states be more consistent in defining the sensitive population. Table 5-1 (pp. 131-132) clearly shows that none of the states agree on how the “sensitive population” should be defined. As noted on p. 131, both PCBs and mercury exhibit developmental effects, but the recommended advisory (Table 1, p. 4) then defines the "sensitive population" as women of reproductive age and young girls. Some organ systems are still developing into teenage years for both boys and girls. Thus, the "sensitive population" should include boys as well as girls..

4. The distinctions between “migratory” and “nonmigratory” and “coastal vs. noncoastal (spawning)” are not adequately defined. and thus can be confusing.

5. The report states that “The mid Atlantic state advisories are dominated by spawning-location-specific advisories and a lack of advisories on coastal waters impacting migratory fish.” The latter statement is not necessarily true – e.g., NYSDOH has a 1 meal/month advisory for western LI Sound striped bass and 1 meal/week advisories for Atlantic Ocean & Eastern LI Sound bluefish & striped bass based on measured differences in PCB concentrations in fish from these areas that have been stable over a number of years.

6. In the Conclusions and Recommendations chapter the second paragraph on page 147 states that striped bass advisories for high risk groups in the northeast states are “already very close to consistent.”. Review of the accompanying Table 6-2 indicates otherwise, since some states (e.g., Rhode Island, Connecticut) have advisories to EAT NO coastal striped bass at all, while most of the other states have less restrictive advice (e.g., 1 meal/week for some New York waters) or offer no advisories at all for coastal striped bass.

REFERENCE

Longnecker, M.P., Wolff, M.S., Gladen, B.C., Brock, J.W., Grandjean, P., Jacobson, J.L., Korrick, S.A., Rogan, W.J., Weisglas-Kuperus, N., Hertz-Picciotto, I., Ayotte, P., Stewart, P., Winneke, G., Charles, M.J., Jacobson, S.W., Dewailly, E., Boersma, E.R., Altshul, L.M., Heinzow, B., Pagano, J.J., & Jensen, A.A. 2003. Comparison of polychlorinated biphenyl levels across studies of human neurodevelopment. Environ Health Perspect. 111:65-70.